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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/571,081

03/31/2006

Yaeta Endo

3190-091

1222

33432 7590 10/29/2007  
KILYK & BOWERSOX, P.L.L.C.  
400 HOLIDAY COURT  
SUITE 102  
WARRENTON, VA 20186

EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

10/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/571,081	<b>Applicant(s)</b> ENDO ET AL.	
	<b>Examiner</b> Mary E. Mosher, Ph.D.	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/6/06, 5/10/06, 8/25/06</u> | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group I, species (+) RNA virus, RNA polymerase protein, autoproteolysis activity in the reply filed on 8/20/07 is acknowledged. The traversal is on the ground(s) that unity exists because the PCT search authority examined all of the claims, and examination of all of the claims would not be burdensome because the search for the claims would overlap. This is not found persuasive because the findings of the international search authority are not binding upon the national stage application, applicant did not address the reasons for finding a lack of unity, and because search of the various inventions is not co-extensive

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/20/2007.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinz et al (Antimicrobial Agents and Chemotherapy 40:267-270, 1996, in IDS) in view of Endo et al (WO 03/064671, in IDS). Note, US 20050042305 is an English language equivalent of Endo et al, and passages in the US document are cited for convenience.

Heinz et al teaches an assay to screen drugs to the rhinovirus 3C protease, comprising translating a coding sequence in a cell-free lysate in the presence or absence of candidate protease inhibitor drugs, and measuring autodigestion of the translation product. Rhinovirus is a (+) stranded RNA virus, the protease autodigests, the autodigestion necessarily involves a folding process, and the protease is essential for propagation of the pathogenic rhinovirus. Heinz differs from the claimed invention in that Heinz used a rabbit reticulocyte lysate instead of a wheat germ lysate. However, Endo teaches a wheat germ extract as an alternative to the rabbit reticulocyte assay for cell-free protein synthesis, see for example paragraph 0002 and claims 15-19. Endo also teaches substantial removal of endosperm and low molecular weight inhibitors, see paragraphs 0057-0058. Therefore it would have been obvious to substitute the wheat

germ extract for the rabbit reticulocyte lysate, with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinz et al (Antimicrobial Agents and Chemotherapy 40:267-270, 1996, in IDS) in view of Endo et al (WO 03/064671, in IDS) as applied to claims 1-10 above, and further in view of Anand et al (Science 300:1763-1767, 13 June 2003, published online 13 May 2003, in IDS). Claim 12 differs from the above in specifying a SARS protein. Anand teaches a SARS protease which is structurally similar to the rhinovirus 3C protease, and teaches that inhibitors to the protease are of interest. Therefore it would have been obvious to further modify the method of Heinz by substituting a SARS protease gene for the rhinovirus protease gene, for the purpose of identifying potential anti-SARS drugs. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 1, 3, 5, 6, 8, 9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenten et al US 2003/0207290. Kenten teaches an assay using in vitro transcription and translation. Kenten suggests use of the assay for screening large numbers of proteins for a variety of activities. Kenten also suggests using the same assay for identifying modulators of the activities, see paragraphs 0046-0049. The reference discusses activities of proteases, DNA or RNA polymerases, and helicases, see paragraph 0103, and provides a working example for screening inhibitors of kinase enzyme activity, see Example 28 at paragraphs 0320-0321. Kenten also discusses several oncogene proteins, which are associated with pathogenic proliferation of cells, see for example Tables 36 and 37. See also claims 106-118. Kenten does not use

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wheat germ extracts in the working examples, but Kenten explicitly suggests wheat germ extracts as suitable for the method, see paragraphs 0075 and 0077. It would have been within the ordinary skill of the art to carry out the suggestions made by Kenten, with reasonable expectation of success. The invention as a whole is therefore *prima facie* obvious, absent unexpected results.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Mary E Mosher, Ph.D.  
Primary Examiner  
Art Unit 1648

10/25/07